

Docket No. 1220-2
09/214,645

Patent

REMARKS

With this response, claims 16-39 are currently pending. Independent claims 16 and 17, and dependent claims 18, 24 and 29 have been amended. Support for the amendments to claims 16 and 17 can be found throughout the specification. Claim 18 has been amended to provide proper Markush format and to correct a grammatical error. Claim 24 has been amended to provide proper antecedent basis. Claim 29 has been amended to correct a grammatical error. No new matter has been added.

Non Art-Based Rejections

Objections Under 32 U.S.C. 132

In the Office action, the specification was objected to on the basis that material added to page 14 of the specification in the Supplemental Amendment filed March 6, 2003 constitutes new matter. Applicant respectfully traverses this objection. As stated in the Supplemental Amendment, the text added to page 14 was taken from the figures as originally filed with the Patent Office. The text can also be found in International Application PCT/US97/12239, of which the present application is the national phase thereof. It is well established that the drawings are part of the disclosure and that the amendment of the specification to include material contained in the drawings as filed does not constitute the addition of new matter. *In re Heinle*, 342 F.2d 1001 (C.C.P.A. 1965). Applicant therefore respectfully requests reconsideration and withdrawal of this objection.

Objections Under 37 C.F.R. 1.52(c)

The specification was further objected to as containing alterations that have not been initialed and/or dated as required by 37 CFR 1.52(c) and cites page 30 of the specification as an example. Applicant thanks the Examiner for taking the time to research and discuss the issue with the Applicant's representative. It is Applicant's understanding that the alterations objected to were amendments that were previously entered, but not identified as amendments. Applicant, therefore, believes this issue to be moot and respectfully requests withdrawal of the objection.

Docket No. 1220-2
09/214,645

Patent

Informalities

In the Office action, the specification was objected to because it makes reference to U.S. Patent Applications but does not indicate the current status of same. With this response, the specification has been amended to include the current status of the referenced U.S. Patent Applications. In light of this amendment, Applicant respectfully requests that this objection be withdrawn.

Rejections Under 35 U.S.C. 112, First Paragraph

In the Office action, claims 16-39 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. In particular the Office action construed the claims as requiring that a nucleic acid encoding a polypeptide having virtually any property be produced by the claimed method. With this response, claims 16 and 17 have been amended such that the claims do not require production of a polynucleotide encoding a polypeptide having the desired activity, but rather that the mutagenized products of the method are selected for the desired property. Thus, the claims, as presently amended, do not require that a polynucleotide encoding a desired be actually produced, but rather that mutagenized polynucleotides be produced followed by selection for polypeptides having the desired property.

The purpose of the enablement requirement of § 112 "is to assure that the inventor provides sufficient information about the claimed invention that a person of skill in the filed of the invention can make and use it without undue experimentation, relying on the patent specification and the knowledge in the art." *Scripps Clinic & Research Found. v. Genetech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). How a teaching is set forth, whether by specific example or broad terminology is not important. *In re Wright*, 999 F2d 1557, 1561 (Fed. Cir. 1993).

The burden of showing lack of enablement rest with the Patent Office. "[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 439 F.2d 220, 223 (Fed. Cir. 1971) (emphasis in original). The Office Action does not allege that the

Docket No. 1220-2
09/214,645

Patent

specification does not enable the production of random sized fragments, along with their isolation, shuffling and screening. To the contrary, the Patent Office admits on page 4 of the Office action that the specification contains examples of these processes. Rather, the enablement rejection is based on the assertion that the process will not necessarily result in a polynucleotide encoding a polypeptide having a desired property. As noted above, however, independent claims 16 and 17 have been amended to require only that mutagenized polynucleotides be produced and that the mutagenized polypeptides be screened for those that encode polypeptides having the desired property.

That some of the mutagenized polypeptides produced by the claimed method will not encode a polypeptide having the desired property does not result in a failure to meet the enablement requirement of § 112. It is well established that "[e]ven if some of the claimed combinations [a]re inoperative, the claims are not necessarily invalid. It is not a function of the claims to specifically exclude possible inoperative substances." *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984) (internal quotes and punctuation omitted). This is true even in unpredictable arts. See *In re Angstadt*, 537 F.2d 498 (C.C.P.A. 1976). All that is required is that one skilled in the art be able to determine combinations which do not work without undue experimentation. *In re Angstadt* 537 F.2d at 503. It is not required for enablement that one skilled in the art be able to determine with certainty, prior to the reaction, that the desired product will be obtained. *Id.* Further, the burden is on the Patent Office to provide reasons, supported by the record as a whole, that the amount of experimentation required is undue. *Id.*

The fact that the claims may cover a wide variety of potential products also does not result in a failure to meet the enablement requirement. As long as the specification is sufficient to guide those skilled in the art, the enablement requirement is met, even if the process is one dealing with a large class of substances and ranges of treatments leaving something to the skill of the persons applying the invention. *In re Angstadt*, 537 F.2d at 504. If the performance of trial runs is practiced in the art, then such experimentation is not unreasonable and applicants should be allowed to claim the broad range of processes that they have discovered. *Id.*

Applicant contends that the claims, as amended, are fully enabled. The specification provides guidance such that one skilled in the art can produce mutagenized polynucleotides

Docket No. 1220-2
09/214,645

Patent

suitable for screening. Applicant further contends that the screening of polypeptides expressed by mutagenized polynucleotides for desired properties is routine within the fields of biochemistry and molecular biology. For example, and without limitation, polypeptides are routinely screened for enzymatic activity, antigen binding activity, receptor binding activity, nucleic acid binding activity, thermal stability, pH stability, resistance or susceptibility to proteolysis, etc. To meet the enablement requirement the Applicant is not required to disclose all possible properties or selection methods that could be employed in the invention. As stated by the courts, "such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area..." *In re Angstadt*, 537 F.2d 498, 502-503 (C.C.P.A. 1976). In light of the present amendments and arguments, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 16-39 under 35 U.S.C. 112, first paragraph.

Art-Based Rejections

Applicant acknowledges that no claims currently stand rejected under 35 U.S.C. 102 or 35 U.S.C. 103.

PETITION FOR EXTENSION OF TIME

Applicant herewith petitions for a 3 month extension of time to reply under 37 C.F.R. 1.136. The Commissioner is herewith authorized to charge Deposit Account No. 50-0661 the amount of \$475.00 as set forth in 37 C.F.R. 1.17(a)(3). If Applicant has made an error in calculating the amount due, the Commissioner is herewith authorized to charge any underpayment or credit any overpayment that may occur during the pendency of this application to Deposit Account No. 50-0661.

CONCLUSION

In light of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and withdrawal of all rejections set forth in the Office action of July 16, 2003.

Page 11 of 12

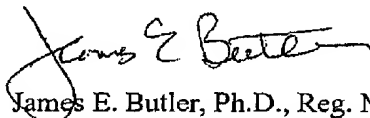
Docket No. 1220-2
09/214,645

Patent

Further, Applicant respectfully submits that all claims presently under consideration are in a condition for allowance and requests issuance of a Notice of Allowance at the Examiner's earliest convenience.

Should the Examiner have any remaining questions regarding the subject invention or its patentability, Applicant encourages the Examiner to contact the undersigned to answer such questions or provide additional information.

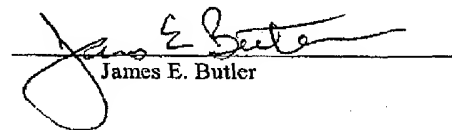
Respectfully submitted,



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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the above RESPONSE UNDER 37 C.F.R. 1.111 in the application of Jay M Short, Serial No. 09/214,645, filed September 27, 1999, is being submitted to the Commissioner for Patents by facsimile transmission to telephone number (703) 872-9306 on this 15th day of January, 2004.


James E. Butler